

# Environmental Risk Assessment at JRF Global

For veterinary products



The introduction of Veterinary Medicinal Products (VMPs) into the European Legislation (Directive 92/18/EC) products require a 2-step process to evaluate its properties with regards to environmental risk assessment. As per the VICH GL6 Guideline, the first phase describes the estimation of exposure using different models that take into account the method of administration, target species and characteristics of the constituents of the VMP.

The second phase includes testing of the fate and effects of the residue based on the results from the first phase. The VICH GL38 guideline describes the


details of the second phase of the study. It uses a two-tiered approach with an initial set of Physico-chemical, ecotoxicity and e-fate studies to produce a conservative assessment. Additional testing may be needed based on the results and the branch of application.

JRF Global offers a comprehensive package for Environmental Risk Assessment studies for global submissions, including Toxicology, Product Chemistry, Ecotoxicology, and Efate studies. These studies offered as per the regulatory requirements from USEPA, EU, Japan etc regulators and in compliance with global guidelines.

## TIER A

## COMMENTS

## TIER B

 <b>Physical-Chemical Properties</b>		
OECD 101 UV-Visible Absorption Spectrum		
OECD 102 Melting Point/Melting Range		
*OECD 104 Vapour Pressure		
OECD 105 Water Solubility		
OECD 107 or 117 n-Octanol/Water Partition Coefficient	OECD 123 If $\geq 4$ TIER 2	



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## TIER A

## COMMENTS

## TIER B



### Environmental fate studies

OECD 106 Soil Adsorption/Desorption\*

$K_{oc}$  and  $K_d$  values for a range of soils

OECD 307 Soil Biodegradation (route and rate)\*\*

Recommended only for the terrestrial and aquaculture branches

OECD 308 Degradation in aquatic systems\*\*

Recommended only for the terrestrial and aquaculture branches

Photolysis (optional) Seek regulatory guidance\*\*\*

OECD 111 Hydrolysis (optional)

If  $\log K_{ow} \geq 4$  TIER 2

OECD 305 Fish Bioaccumulation



### Aquatic effects studies

OECD 201 Freshwater Algal growth inhibition

If RQ for the affected taxonomic level is  $\geq 1$  following use of the PEC<sub>refined</sub>

OECD 201 with NOEC

OECD 202 Freshwater Daphnia immobilization

OECD 211 Daphnia magna Reproduction

OECD 203 Freshwater Fish acute toxicity

OECD 210: Fish early-life Stage

Saltwater studies



### Terrestrial studies

OECD 216 Nitrogen Transformation (28 days)\* < 25% of control \*\*

RQ for the affected taxonomic levels is  $\geq 1$  or in the case of soil micro-organisms an effect > 25% following use of the PEC<sub>refined</sub>

Nitrogen Transformation (100 days extension of Tier A study)

OECD 208 Terrestrial plants EC<sub>50</sub> 100

Terrestrial plants growth, more species from most sensitive category

OECD 220 /222 Earthworm Subacute/reproduction NOEC 10

### Additional effects studies recommended for endo/ectoparasiticides used for pasture treatments at Tier A

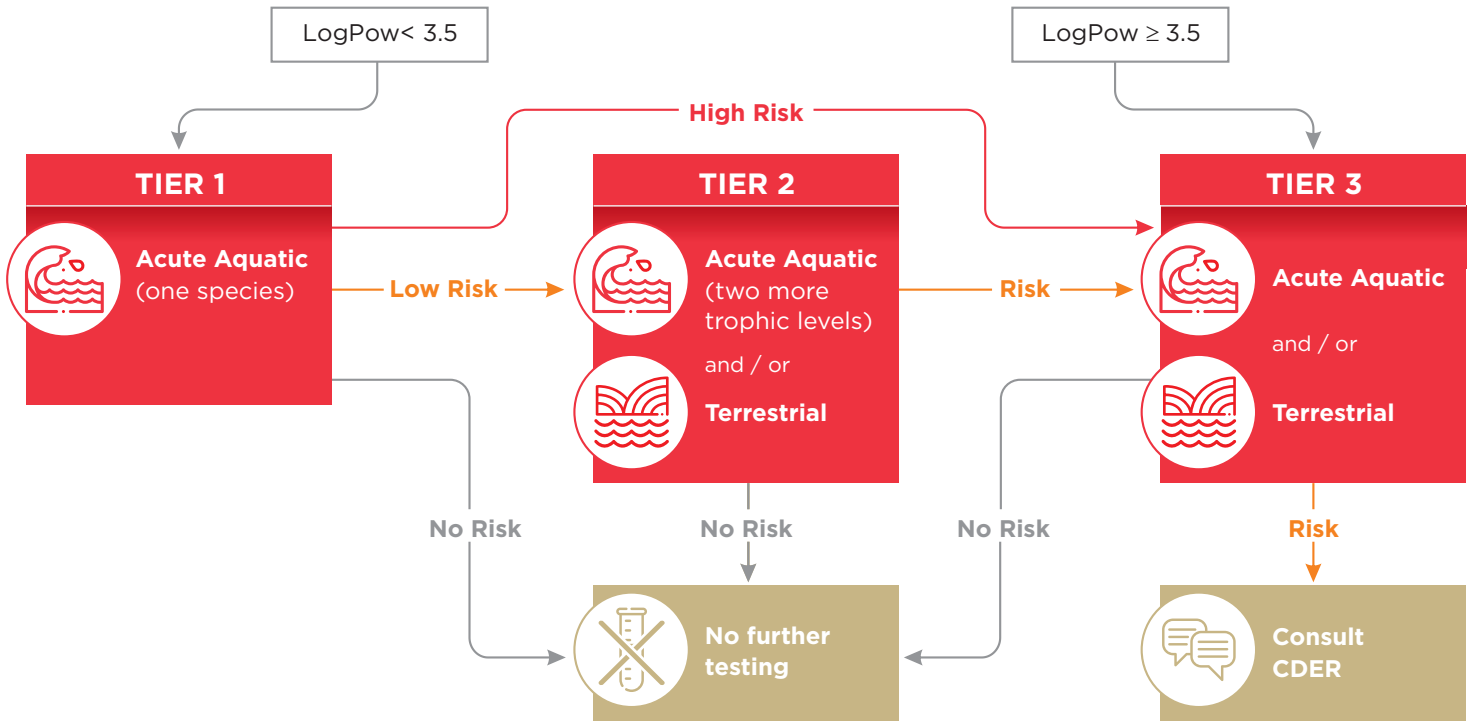
Dung fly larvae

NA

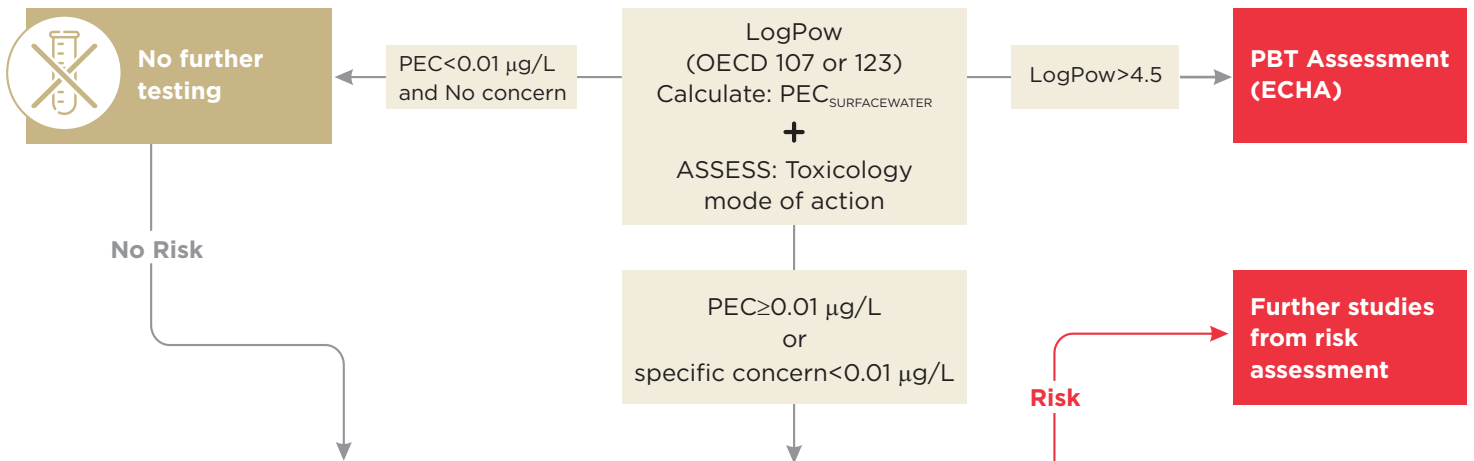
Dung beetle larvae

NA

## ERA approach for medicinal products for human use (USFDA)



## ERA approach for medicinal products for human use (EMA)



- |    |   |                                       |    |
|----|---|---------------------------------------|----|
| 01 | Adsorption/Description - OECD 106                       | Daphnia reproduction test - OECD 211  | 05 |
| 02 | Activated sludge respiration inhibition test - OECD 209 | Fish early life stage test - OECD 210 | 06 |
| 03 | Algal growth inhibition test                            | Water sediment study - OECD 308       | 07 |
| 04 | Biodegradation - OECD 301                               | Tests for specific concerns if any    | 08 |

Not for veterinary use



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JRF India | JRF America | JRF Europe  
Contact us at [bd@jrfglobal.com](mailto:bd@jrfglobal.com) | [www.jrfglobal.com](http://www.jrfglobal.com)

